IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ACADIA PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 1:20-cv-01029-RGA
	)	
MSN LABORATORIES PRIVATE LTD. and MSN PHARMACEUTICALS, INC.,	)	
	)	
Defendants.	)	

ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Defendants MSN Laboratories Private Limited ("MSN Labs") and MSN Pharmaceuticals, Inc. ("MSN Pharma") (collectively, "MSN" or "Defendants"), by their undersigned attorneys, for their Answer to the Complaint for Patent Infringement filed by Plaintiff ACADIA Pharmaceuticals Inc. ("ACADIA" or "Plaintiff") filed July 30, 2020, respond as follows. Pursuant to Fed. R. Civ. P. 8(b)(3), MSN denies all allegations in Plaintiffs' Complaint except those expressly admitted below.

THE PARTIES

1. ACADIA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 3611 Valley Centre Drive Suite 300, San Diego, California 92130.

ANSWER: MSN is without knowledge or information to form a belief as to the truth of the allegations of Paragraph 1, and therefore denies them.

2. Upon information and belief, MSN Labs is an entity organized and existing under the laws of India, having a principal place of business at MSN House, Plot No. C-24, Industrial Estate, Sanathnagar, Hyderabad, Telangana, 500018 India.

ANSWER: MSN Labs admits that its principal place of business is located at MSN House, Plot No: C-24, Industrial Estate, Sanathnagar, Hyderabad, Telangana, India. MSN Labs denies

the remaining allegations in Paragraph 2.

3. Upon information and belief, MSN Pharma is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854.

ANSWER: Admitted

4. Upon information and belief, MSN Pharma is a wholly owned subsidiary of MSN Labs.

ANSWER: Admitted

5. Upon information and belief, MSN Pharma acts at the direction, and for the benefit, of MSN Labs and is controlled and/or dominated by MSN Labs.

ANSWER: Paragraph 5 of the Complaint contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, MSN denies the allegations in Paragraph 5.

6. Upon information and belief, MSN Labs and MSN Pharma work in concert, either directly or indirectly, with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in the State of Delaware.

ANSWER: Paragraph 6 of the Complaint contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, MSN denies the allegations in Paragraph 6.

7. Upon information and belief, MSN Labs and MSN Pharma have participated and collaborated in the preparation, filing, and seeking FDA approval of Abbreviated New Drug Application ("ANDA") No. 214925 for pimavanserin tartrate oral capsule, EQ 34 mg base ("the MSN Generic Product"); continue to participate and collaborate in seeking FDA approval of ANDA No. 214925; and intend to participate and collaborate in the commercial manufacture, marketing, offer for sale, and/or sale of the MSN Generic Product throughout the United States including in the State of Delaware.

ANSWER: Paragraph 7 of the Complaint contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, MSN admits that it has prepared and filed ANDA No. 214925 and otherwise denies the allegations in Paragraph 7.

NATURE OF THE ACTION

8. This is a civil action for infringement of United States Patent Nos. 7,732,615 ("the '615 patent") and 10,646,480 ("the '480 patent") (collectively "the patents-in-suit"). This action arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*

ANSWER: Paragraph 8 contains conclusions of law for which no response is required. To the extent a response is required, MSN admits that the Complaint purports to bring an action for infringement of U.S. Patent Nos. 7,732,615 ("the '615 patent") and 10,646,480 ("the '480 patent") arising under the United States patent laws, Title 35, United States Code. MSN denies any remaining allegations in this paragraph

JURISDICTION & VENUE

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), 2201, 2202, and 35 U.S.C. § 271. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201-02 because this case is an actual controversy within the Court's jurisdiction.

ANSWER: Paragraph 9 contains conclusions of law for which no response is required. To the extent a response is required, MSN admits that the Complaint cites the patent laws of the United States generally. MSN does not contest subject matter jurisdiction for purposes of this case only. MSN denies the remaining allegations of this paragraph.

10. Upon information and belief, MSN Pharma is a Delaware corporation and has a registered agent in the State of Delaware, United States Corporation Agents, Inc., located at 221 North Broad Street, Suite 3A, Middletown, Delaware 19709.

ANSWER: Denied. The correct address is 300 Delaware Avenue, Suite 210-A, Wilmington, Delaware, 19801.

11. Venue is proper in this Court as to MSN Pharma under 28 U.S.C. §§ 1391(b), (c), (d), and/or 1400(b) because MSN Pharma is incorporated in Delaware and thus resides in this Judicial District. MSN Pharma has also committed and will commit further acts of infringement in this Judicial District. Venue is proper for the additional reasons set forth below, and for other reasons that will be presented to the Court if such venue is challenged.

ANSWER: Paragraph 11 contains conclusions of law for which no response is required. To

the extent a response is required, MSN Pharma does not contest venue for purposes of this case only. MSN denies the remaining allegations of this paragraph.

12. This Court has personal jurisdiction over MSN Pharma, and venue is proper in this Judicial District, by virtue of the facts that, *inter alia*, MSN Pharma is a Delaware corporation and thus resides in Delaware and has committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led to and/or will lead to foreseeable harm and injury to ACADIA, a Delaware corporation, including in the State of Delaware. Upon information and belief, MSN Pharma intends to engage in the commercial manufacture, use, or sale of the MSN Generic Product under ANDA No. 214925 before the expiration of the patents-in-suit, throughout the United States, including in the State of Delaware.

ANSWER: Paragraph 12 contains conclusions of law for which no response is required. To the extent a response is required, MSN Pharma does not contest personal jurisdiction for purposes of this case only. MSN denies the remaining allegations of this paragraph.

13. Upon information and belief, MSN Pharma has purposely availed itself of the privilege of doing business in Delaware, including by, *inter alia*, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in the State of Delaware, through its own actions, and through the actions of its agents and affiliates.

ANSWER: Paragraph 13 contains conclusions of law for which no response is required. To the extent a response is required, MSN Pharma does not contest personal jurisdiction for purposes of this case only. MSN denies the remaining allegations of this paragraph.

14. This Court also has personal jurisdiction over MSN Pharma, and venue is proper in this Judicial District, by virtue of the fact that, upon information and belief, MSN Pharma maintains pervasive, continuous, and systematic contacts with the State of Delaware, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in the State of Delaware, through its own actions and through the actions of its agents and affiliates.

ANSWER: Paragraph 14 contains conclusions of law for which no response is required. To the extent a response is required, MSN Pharma does not contest personal jurisdiction for purposes of this case only. MSN denies the remaining allegations of this paragraph.

15. Venue is proper in this Court as to MSN Labs under 28 U.S.C. §§ 1391(b), (c), (d), and/or 1400(b) because, *inter alia*, MSN Labs, directly or indirectly through its subsidiaries, agents, and/or alter egos, has a regular and established place of business in the State of Delaware,

including, at least, MSN Pharma, a wholly owned subsidiary incorporated in the State of Delaware, and has also committed and will commit further acts of infringement in this Judicial District. Venue is proper for the additional reasons set forth below, and for other reasons that will be presented to the Court if such venue is challenged.

ANSWER: Paragraph 15 contains conclusions of law for which no response is required. To the extent a response is required, MSN Labs does not contest venue for purposes of this case only. MSN denies the remaining allegations of this paragraph.

16. This Court has personal jurisdiction over MSN Labs, and venue is proper in this Judicial District, by virtue of the facts that, *inter alia*, MSN Labs wholly owns a subsidiary that is incorporated in the State of Delaware and has committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led to and/or will lead to foreseeable harm and injury to ACADIA, a Delaware corporation, including in the State of Delaware. MSN Labs has indicated that it intends, directly or indirectly through its subsidiaries, agents, and/or alter egos, to engage in the commercial manufacture, use, or sale of the MSN Generic Product under ANDA No. 214925 before the expiration of the patents-in-suit, throughout the United States, including in the State of Delaware.

ANSWER: Paragraph 16 contains conclusions of law for which no response is required. To the extent a response is required, MSN Labs does not contest personal jurisdiction or venue for purposes of this case only. MSN denies the remaining allegations of this paragraph.

17. Upon information and belief, MSN Labs has purposely availed itself of the privilege of doing business in Delaware, including by, *inter alia*, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in the State of Delaware, through its own actions, and through the actions of its agents and affiliates, including, at least, MSN Pharma.

ANSWER: Paragraph 17 contains conclusions of law for which no response is required. To the extent a response is required, MSN Labs does not contest personal jurisdiction for purposes of this case only. MSN denies the remaining allegations of this paragraph.

18. MSN's website states that "MSN Group is the fastest growing research-based pharmaceutical company based out of India" with "more than 40,000,000 customers across 65 countries globally" and has "nine API and five finished dosage facilities established across Hyderabad, USA and Myanmar." Who We Are, http://www.msnlabs.com/who-we-are.html (last visited July 23, 2010). MSN's website also states that its "reach is now global – not just in markets, but [they] also have offices in New Jersey – USA . . . and a few other international locations." Leader in Drug Development, http://www.msnlabs.com/r-and-d.html (last visited July 23, 2020).

ANSWER: MSN's website speaks for itself. MSN denies the remaining allegations of this paragraph.

19. This Court also has personal jurisdiction over MSN Labs, and venue is proper in this Judicial District, by virtue of the fact that, upon information and belief, MSN Labs maintains pervasive, continuous, and systematic contacts with the State of Delaware, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in the State of Delaware, through its own actions and through the actions of its agents and affiliates, including, at least, MSN Pharma. Upon information and belief, MSN Labs derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in the State of Delaware.

ANSWER: Paragraph 19 contains conclusions of law for which no response is required. To the extent a response is required, MSN Labs does not contest personal jurisdiction for purposes of this case only. MSN denies the remaining allegations of this paragraph.

20. MSN's infringing actions with respect to the filing of ANDA No. 214925 and intent to commercialize the MSN Generic Product have led and/or will lead to foreseeable harm and injury to ACADIA.

ANSWER: Denied.

21. This Court also has personal jurisdiction over MSN Labs and MSN Pharma, and venue is proper in this Court because, *inter alia*, they have previously been sued together in this Judicial District and have not challenged personal jurisdiction or venue, and have purposefully availed themselves of the rights and benefits of the jurisdiction of this Court by filing counterclaims in this Judicial District. *See, e.g.*, *Vanda Pharm. Inc. v. MSN Pharm. Inc.*, C.A. No. 20-0318-CFC (D. Del.) (MSN Labs and MSN Pharma did not contest jurisdiction and filed counterclaims); *Vanda Pharm. Inc. v. MSN Pharm. Inc.*, C.A. No. 20-0235-CFC (D. Del.) (same); *Vanda Pharm. Inc. v. MSN Pharm. Inc.* C.A. No. 19-926-CFC (D. Del.) (same); *Genentech, Inc. v. MSN Labs. Private Ltd.*, C.A. No. 19-0205-RGA (D. Del.) (same); *Boehringer Ingelheim Pharm. Inc. v. MSN Labs. Private Ltd.*, C.A. No. 18-1785-CFC-SRF (D. Del.) (same); *Biogen Int'l GmbH v. MSN Labs Private Ltd.*, C.A. No-18-0337-MN (D. Del.) (same).

ANSWER: Paragraph 21 contains conclusions of law for which no response is required. To the extent a response is required, MSN does not contest personal jurisdiction or venue for purposes of this case only. MSN denies the remaining allegations of this paragraph.

22. Alternatively, should the Court find that the above facts do not establish personal jurisdiction over MSN Labs in this action, this Court may exercise jurisdiction over MSN Labs

pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) ACADIA's claims arise under federal law; (b) MSN Labs is a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) MSN Labs has sufficient contacts with the United States as a whole, including, but not limited to, submitting various ANDAs to the FDA, and manufacturing and selling active pharmaceutical ingredients that are used in the products distributed throughout the United States, such that this Court's exercise of jurisdiction over MSN Labs satisfies due process.

ANSWER: Paragraph 22 contains conclusions of law for which no response is required. To the extent a response is required, MSN does not contest personal jurisdiction for purposes of this case only. MSN denies the remaining allegations of this paragraph.

ACADIA'S NDA AND THE PATENTS-IN-SUIT

23. ACADIA holds New Drug Application ("NDA") No. 210793 for oral capsules containing pimavanserin tartrate, Eq. 34 mg base as the active ingredient. ACADIA exclusively manufactures, markets, and sells these oral capsules in the United States under the brand name NUPLAZID®.

ANSWER: MSN admits that according to the Orange Book ACADIA is the apparent holder of New Drug Application ("NDA") No. 210793 for oral capsules containing pimavanserin tartrate, Eq. 34 mg base as the active ingredient. MSN lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and, therefore, denies them.

24. On June 8, 2010, the '615 patent, entitled "N-(4-fluorobenzyl)-N-(1- methylpiperidin-4-yl)-N′-(4-(2-methylpropyloxy)phenylmethyl)carbamide and its tartrate salt and crystalline forms" was duly and legally issued. A copy of the '615 patent is attached as Exhibit A.

ANSWER: MSN admits that the '615 patent is entitled "N-(4-fluorobenzyl)-N-(1-methylpiperidin-4-yl)-N′-(4-(2-methylpropyloxy)phenylmethyl)carbamide and its tartrate salt and crystalline forms" and that a purported copy of the '615 patent is attached as Exhibit A to the Complaint. MSN admits that the '615 patent indicates on its face an issue date of June 8, 2010. MSN denies the '615 patent was duly and legally issued. MSN denies the remaining allegations of this paragraph.

25. ACADIA owns the '615 patent.

ANSWER: MSN lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this Paragraph 25 and, therefore, denies them.

26. On May 12, 2020, the '480 patent, entitled "Formulations of pimavanserin" was duly and legally issued. A copy of the '480 patent is attached as Exhibit B.

ANSWER: MSN admits that the '480 patent is entitled "Formulations of pimavanserin" and that a purported copy of the '480 patent is attached as Exhibit B to the Complaint. MSN admits that the '480 patent indicates on its face an issue date of May 12, 2020. MSN denies the '480 patent was duly and legally issued. MSN denies the remaining allegations of this paragraph.

27. ACADIA owns the '480 patent.

ANSWER: MSN lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this Paragraph 27 and, therefore, denies them.

28. Pursuant to 21 U.S.C. § 355(b)(1), the patents-in-suit are listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") as covering NUPLAZID® or its use.

ANSWER: Paragraph 28 contains legal conclusions to which no response is required. To the extent that a response is required, MSN admits that the patents identified in paragraph 32 are listed in the Orange Book in connection with NUPLAZID® or its use, and denies any remaining allegations in paragraph 28.

MSN'S ANDA AND PARAGRAPH IV NOTIFICATION

29. Upon information and belief, MSN submitted ANDA No. 214925 to the FDA under 21 U.S.C. § 355(j). Upon information and belief, MSN's ANDA No. 214925 seeks FDA approval to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the MSN Generic Product prior to the expiration of the patents-in-suit.

ANSWER: MSN admits that it submitted ANDA No. 214925 to the FDA under 21 U.S.C. § 355(j). MSN denies the remaining allegations in this paragraph.

30. Upon information and belief, by filing ANDA No. 214925, MSN has certified to the FDA that the MSN Generic Product has the same active ingredient as NUPLAZID® and the same or substantially the same proposed labeling as NUPLAZID®.

ANSWER: MSN admits that its Pimavanserin Tartrate capsule, Eq. 34 mg base product, for which ANDA No. 214925 was submitted to the FDA ("MSN ANDA Product") contains the active ingredient Pimavanserin Tartrate. MSN admits that the proposed label for the MSN ANDA Product states that it is indicated for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis. MSN denies the remaining allegations in this paragraph.

31. ACADIA received written notifications of MSN's ANDA No. 214925 and its accompanying § 505(j)(2)(A)(vii)(IV) certification by two letters, one dated June 15, 2020 ("MSN's 6/15 Notice Letter") and one dated June 18, 2020 ("MSN's 6/18 Notice Letter") (collectively, "MSN's Notice Letters").

ANSWER: MSN admits that by two Notice Letters, dated June 15 and June 18, 2020, it notified ACADIA that MSN had submitted ANDA No. 214925, which contained Paragraph IV certifications.

32. MSN's Notice Letters represent that MSN certified in ANDA No. 214925 that the claims of the patents-in-suit are invalid or would not be infringed by the commercial manufacture, use, sale, or offer for sale of the MSN Generic Product.

ANSWER: Admitted.

33. According to applicable regulations, Notice Letters such as MSN's Notice Letters must contain a detailed statement of the factual and legal bases for the applicant's opinion that the patent is invalid, unenforceable, or not infringed, which includes a claim-by-claim analysis, describing "[f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." *See* 21 C.F.R. § 314.95(c)(7); *see also* 21 C.F.R. § 314.52.

ANSWER: Paragraph 33 contains legal conclusions to which no response is required. To the extent that a response is required, MSN denies any allegations in paragraph 33.

34. This action is being commenced by ACADIA within 45 days of its receipt of MSN's Notice Letters.

ANSWER: MSN admits that the Complaint was filed within 45 days of June 15, 2020. MSN denies any remaining allegations.

COUNT I – INFRINGEMENT
BY MSN LABS AND MSN PHARMA

35. ACADIA re-alleges paragraphs 1-34 as if fully set forth herein.

ANSWER: MSN repeats and incorporates by reference its answers to paragraphs 1-34 as if fully set forth herein.

36. MSN's submission of ANDA No. 214925 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the patents-in-suit under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

37. Upon information and belief, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), MSN certified in ANDA No. 214925 that the claims of the patents-in-suit are invalid, unenforceable, or would not be infringed by the commercial manufacture, use, sale, or offer for sale of the MSN Generic Product. MSN notified ACADIA of that certification and provided a statement of the alleged bases for its claims.

ANSWER: Admitted.

38. MSN's 6/15 Notice Letter represented that ANDA No. 214925 included a §505(j)(2)(A)(vii)(IV) certification with respect to the '615 patent.

ANSWER: Admitted.

39. MSN's 6/18 Notice Letter represented that ANDA No. 214925 included a §505(j)(2)(A)(vii)(IV) certification with respect to the '480 patent.

ANSWER: Admitted.

40. MSN's Notice Letters do not identify any factual basis for, or any opinion of, invalidity regarding the claims of any of the patents-in-suit.

ANSWER: Although MSN admits that its Notice Letters do not set forth specific invalidity arguments, MSN's Notice Letters reserved the right to assert any invalidity defense that may arise.

41. Defendants are jointly and severally liable for infringement of the patents-in-suit under 35 U.S.C. § 271(e)(2)(A). Upon information and belief, Defendants actively and knowingly

caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 214925 seeking to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the MSN Generic Product prior to the expiration of the patents-in-suit.

ANSWER: MSN admits that it submitted ANDA No. 214925. All other allegations are denied.

42. Upon information and belief, MSN was aware of the existence of the patents-in-suit and were aware that the filing of ANDA No. 214925 and certification with respect to the patents-in-suit constituted an act of infringement of those patents.

ANSWER: Upon information and belief, MSN was and is aware of the existence of the patents-in-suit to the extent that MSN was able to accurately and in good faith certify that the MSN ANDA Product does not infringe the patents-in-suit and/or that the patent-in-suit are invalid and/or unenforceable. MSN otherwise denies the allegations in Paragraph 42.

43. MSN filed ANDA No. 214925 without adequate justification for asserting that the patents-in-suit are invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the MSN Generic Product.

ANSWER: MSN admits that it submitted ANDA No. 214925. All other allegations are denied.

44. Moreover, if MSN manufactures, uses, offers for sale, or imports into the United States any of the MSN Generic Product, or induces or contributes to any such conduct, prior to the expiration of the patents-in-suit, including any applicable exclusivities or extensions, it would infringe one or more claims of the patents-in-suit under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Denied.

45. ACADIA is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of MSN's ANDA No. 214925 be a date that is not earlier than the expiration of the patents-in-suit, or any later expiration of exclusivity for the patents-in-suit to which ACADIA is or becomes entitled.

ANSWER: Denied.

46. ACADIA will be irreparably harmed by MSN's infringing activities unless those activities are enjoined by this Court. ACADIA does not have an adequate remedy at law.

ANSWER: Denied.

PRAYER FOR RELIEF

MSN denies that Plaintiff is entitled to any of the relief requested in their Prayer for Relief or any relief whatsoever.

MSN'S AFFIRMATIVE DEFENSES

Further answering the Complaint, MSN asserts the following defenses in response to the allegations of the Complaint, undertaking the burden of proof only as to those defenses required by law, regardless of how such defenses are denominated below. MSN reserves the right to amend this Answer with additional defenses as further information is obtained. MSN asserts the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted.

FIRST DEFENSE

The '615 patent and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112, or under other judicially-created bases for invalidation, such as double patenting.

SECOND DEFENSE

The '480 patent and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112, or under other judicially-created bases for invalidation, such as double patenting.

THIRD DEFENSE

The filing of ANDA No. 214925 has not infringed and does not infringe any valid and enforceable claim of the '615 and '480 patents, either directly or indirectly, and literally or under the doctrine of equivalents.

FOURTH DEFENSE

The manufacture, use, sale, or offer for sale of the product that is the subject of ANDA No. 214925 has not infringed, and would not, if marketed, infringe any valid and enforceable claim of the '615 and '480 patents, either directly or indirectly, and literally or under the doctrine of

equivalents.

FIFTH DEFENSE

Plaintiff's enforcement of the'615 and '480 patents against MSN is barred by the doctrine of prosecution history estoppel by reason of amendment, cancellation, abandonment, statements, and/or admissions made during prosecution of the '615 and '480 patents and/or related patents before the United States Patent and Trademark Office.

SIXTH DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

SEVENTH DEFENSE

The Complaint fails to state a claim for relief against MSN for exceptional case under 35 U.S.C. § 285.

EIGHTH DEFENSE

MSN has not willfully infringed any claim of the '615 and '480 patents.

NINTH DEFENSE

Any additional defenses that discovery may reveal.

WHEREFORE, MSN respectfully requests that Plaintiff takes nothing by way of its Complaint, that judgment be entered in favor of MSN, and that MSN be awarded its attorneys' fees and costs, and all other just and proper relief.

COUNTERCLAIMS

Defendants and Counterclaim Plaintiffs MSN Laboratories Private Limited ("MSN Labs") and MSN Pharmaceuticals Inc. ("MSN Pharma")(collectively "MSN" or "Counterclaim Plaintiffs") by way of their counterclaims against Plaintiff-Counterclaim Defendant ACADIA Pharmaceuticals Inc. ("Counterclaim Defendant" or "ACADIA") state as follows:

NATURE OF THE ACTION

1. This is an action for declaratory judgment of noninfringement and invalidity of one

or more claims of U.S. Patent Nos. 7,732,615 ("the '615 patent") and 10,646,480 ("the '480 patent") under the Patent Laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*. The '615 patent and '480 patent were attached to Counterclaim Defendant's Complaint.

PARTIES

2. Counterclaimant MSN Labs is a private limited company organized under the laws of India and its principal place of business is located at MSN House, Plot No: C-24, Industrial Estate, Sanathnagar, Hyderabad – 18 Telangana, India.

3. Counterclaimant MSN Pharma is a corporation organized under the laws of Delaware and its principal place of business is located at 20 Duke Road, Piscataway, NJ 08854. MSN Pharma is a wholly owned subsidiary of MSN Labs.

4. On information and belief, Counterclaim Defendant ACADIA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 3611 Valley Centre Drive Suite 300, San Diego, California 92130.

JURISDICTION AND VENUE

5. This court has subject matter jurisdiction over these counterclaims for declaratory judgment pursuant to 28 U.S.C. § 2201, and 2202 based on an actual controversy between MSN, on one hand, and Counterclaim Defendant.

6. These counterclaims arise under the patent laws of the United States, Title 35 of the United States Code. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This court has personal jurisdiction over Counterclaim Defendant ACADIA based, *inter alia*, on the filing of its Complaint here and because Counterclaim Defendant ACADIA is doing business in this jurisdiction.

8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and

1400(b).

9. There is an actual and justiciable controversy between the parties as to the infringement and invalidity of the '615 patent and the '480 patent (collectively, "the patents-in-suit").

FACTUAL BACKGROUND

FDA Approval of New Brand Name Drugs

10. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 et seq., as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration ("FDA") follows when considering whether to approve the marketing of both brand-name and generic drugs.

11. Under the FFDCA, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the FDA. *See* 21 U.S.C. § 355.

12. An NDA must include, among other things, the number of any patent that allegedly claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. See 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b)(1), (c)(2).

13. Upon approval of the NDA, the FDA publishes patent information for the approved drug in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 C.F.R. § 314.53(e).

14. The FDA's duties with respect to the Orange Book listings are purely ministerial. If the NDA-holder submits a patent to the FDA for listing in the Orange Book, the patent is listed in the Orange Book. *See* 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(e)-(f). The FDA does not substantively review the submitted patent information to ensure that it is accurate or that the NDA holder properly submitted it in connection with the NDA drug (or "reference listed drug"), but instead relies on the NDA holder to properly list the patents.

FDA Approval of New Generic Drugs

15. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, to the FFDCA. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). Congress passed the Hatch-Waxman Amendments, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition.

16. Under the Hatch-Waxman Amendments, a generic manufacturer submits to the FDA what is called an Abbreviated New Drug Application ("ANDA").

17. Among other things, an ANDA must also contain a "certification" to each patent that the NDA holder has submitted to the FDA for listing in the Orange Book in connection with the reference listed drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

18. A "Paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, the applicant seeks FDA approval of the generic product prior to patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see also* 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

19. An applicant submitting an ANDA containing a Paragraph IV certification must notify both the patent holder and NDA holder of each of its Paragraph IV certifications. *See* 21 U.S.C. § 355(j)(2)(B).

20. Upon receiving notice of the Paragraph IV certifications, the patent holder has 45 days in which to file an infringement suit against the generic manufacturer. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2)(A).

21. Patent holders have a significant strategic incentive to file suit within 45 days of receiving notice of the Paragraph IV certifications because doing so, regardless of merit, automatically prevents the FDA from approving the generic maker's ANDA for a period of 30 months, absent certain exceptions. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

22. If the court hearing the infringement action decides the patent is valid, enforceable, and would be infringed by the product proposed in the ANDA, the FDA will not approve ANDA until the patent expires. *Id.* If, however, the court hearing the infringement action rules before the expiration of the 30-month period that the patent is invalid, unenforceable, or not infringed, "including any substantive determination that there is no cause of action for patent infringement or invalidity," the FDA may approve the ANDA effective on the date when the court enters the judgment. *Id.*

MSN's ANDA

23. MSN submitted its ANDA No. 214925 seeking approval to engage in the commercial use, manufacture, sale, offer for sale, or importation into the United States of Pimavanserin Tartrate capsule, Eq. 34 mg base ("MSN's ANDA Product"), before the expiration of the patents-in-suit.

24. Upon information and belief, the FDA lists ACADIA as the holder of New Drug Application ("NDA") No. 210793 for NUPLAZID®.

25. In its Complaint, ACADIA alleges it is the assignee of the '615 and '480 patents.

26. On June 15, 2020, MSN sent Counterclaim Defendant ACADIA a letter ("MSN's 6/15 Notice Letter") pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95. MSN's June 15, 2020 Notice Letter advised Counterclaim Defendant of the filing of ANDA No. 214925 for the MSN ANDA Product and contained Paragraph IV certifications for at least the '615 patent, which was listed in the Orange Book in relation to NUPLAZID® at the time MSN submitted its ANDA No. 214925.

27. On June 18, 2020, MSN sent Counterclaim Defendant ACADIA a letter ("MSN's 6/18 Notice Letter") pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95. MSN's June 18, 2020 Notice Letter advised Counterclaim Defendant of

the filing of ANDA No. 214925 for the MSN ANDA Product and contained Paragraph IV certifications for at least the '480 patent, which was listed in the Orange Book in relation to NUPLAZID® after MSN submitted its ANDA No. 214925.

28. MSN's Notice Letters also contained an Offer of Confidential Access (OCA) pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III) to allow Counterclaim Defendant the opportunity to review the relevant portions of MSN's ANDA.

29. Counterclaim Defendant has alleged in the present action that MSN has infringed and will infringe the '615 and '480 patents by filing ANDA No. 214925 with the FDA and/or by manufacturing, using, offering for sale, selling or importing the product described in the ANDA.

30. As a consequence of the foregoing, there is an actual and justiciable controversy between MSN and Counterclaim Defendant as to whether the claims of the '615 and '480 patents are invalid and/or unenforceable, and whether those claims are being infringed or will be infringed by MSN's ANDA No. 214925.

FIRST COUNT
(Declaratory Judgment of Noninfringement of the '615 Patent)

31. MSN repeats and incorporates by reference each of the foregoing paragraphs of MSN's Answer and Affirmative Defenses to the Complaint and of these Counterclaims as if fully set forth herein.

32. This counterclaim arises under the Patent Laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq*. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between MSN and Counterclaim Defendant concerning the infringement of the claims of the '615 patent.

33. Counterclaim Defendant alleges ownership of the '615 patent and has brought

claims against MSN alleging infringement of the '615 patent.

34. The submission of MSN's ANDA No. 214925 does not infringe any valid or enforceable claim of the '615 patent.

35. The manufacture, use, sale and/or offer for sale of the MSN ANDA Product would not infringe any valid or enforceable claim of the '615 patent, either directly, indirectly, or by inducement, and either literally or under the doctrine of equivalents, including because the claims of the '615 patent are invalid, as set forth below in the Second Count of MSN's counterclaims, and an invalid claim cannot be infringed. *See Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1580 (Fed. Cir. 1983) ("It is axiomatic that one cannot infringe an invalid patent.").

36. Further, Counterclaim Defendant bears the burden of proving by preponderant evidence that every limitation set forth in each asserted claim is found in the MSN ANDA Product, either literally or under the doctrine of equivalents. To date, Counterclaim Defendant has not set forth any evidence attempting to prove infringement of any claim of the '615 patent.

37. MSN reserves the right to provide additional bases for noninfringement of the '615 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

38. A present, genuine, and justiciable controversy exists between MSN, on the one hand, and Counterclaim Defendant, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, or sale of the MSN ANDA Product would infringe any valid or enforceable claim of the '615 patent.

39. MSN is entitled to a declaration that the manufacture, use, offer for sale, and sale of the MSN ANDA Product described in ANDA No. 214925 does not and will not infringe any valid claim of the '615 patent.

SECOND COUNT
(Declaratory Judgment of Invalidity of the '615 Patent)

40. MSN repeats and incorporates by reference each of the foregoing paragraphs of MSN's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

41. This counterclaim arises under the Patent Laws of the United States, Title 35 United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq*. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between MSN and Counterclaim Defendant concerning the validity of the claims of the '615 patent.

42. Counterclaim Defendant alleges ownership of the '615 patent and asserts that the commercial manufacture, use, sale and/or offer for sale of the MSN ANDA Product would infringe one or more claims of the '615 patent.

43. MSN asserts that the manufacture, use, offer for sale, or sale of the MSN ANDA Product does not and will not infringe, either directly or indirectly, any valid claim of the '615 patent and that the claims of the '615 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, or 112, or other judicially-created bases for invalidation.

44. The '615 patent is invalid under one or more provisions of 35 U.S.C. §§ 100 *et seq.*, including 101, 102, 103, or 112, or other judicially-created bases for invalidation, such as double patenting.

45. MSN reserves the right to provide additional prior art and bases for invalidity in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

46. MSN is entitled to a declaration that the claims of the '615 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, or 112, or other judicially created bases for invalidation.

THIRD COUNT
(Declaratory Judgment of Noninfringement of the '480 Patent)

47. MSN repeats and incorporates by reference each of the foregoing paragraphs of MSN's Answer and Affirmative Defenses to the Complaint and of these Counterclaims as if fully set forth herein.

48. This counterclaim arises under the Patent Laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq*. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between MSN and Counterclaim Defendant concerning the infringement of the claims of the '480 patent.

49. Counterclaim Defendant alleges ownership of the '480 patent and has brought claims against MSN alleging infringement of the '480 patent.

50. The submission of MSN's ANDA No. 214925 does not infringe any valid or enforceable claim of the '480 patent.

51. The manufacture, use, sale and/or offer for sale of the MSN ANDA Product would not infringe any claims of the '480 patent, either directly, indirectly, or by inducement, and either literally or under the doctrine of equivalents, including because the claims of the '485 patent are invalid, as set forth below in the Fourth Count of MSN's counterclaims, and an invalid claim cannot be infringed. *See Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1580 (Fed. Cir. 1983) ("It is axiomatic that one cannot infringe an invalid patent.").

52. Further, Counterclaim Defendant bears the burden of proving by the preponderance of the evidence that every limitation set forth in each asserted claim is found in the MSN ANDA Product, either literally or under the doctrine of equivalents. To date, Counterclaim Defendant has not set forth any evidence attempting to prove infringement of any claim of the '480 patent.

53. MSN reserves the right to provide additional bases for noninfringement of the '480 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

54. A present, genuine, and justiciable controversy exists between MSN, on the one hand, and Counterclaim Defendant, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, or sale of the MSN ANDA Product would infringe any valid or enforceable claim of the '480 patent.

55. MSN is entitled to a declaration that the manufacture, use, offer for sale, and sale of the MSN ANDA Product described in ANDA No. 214925 does not and will not infringe any valid claim of the '480 patent.

FOURTH COUNT
(Declaratory Judgment of Invalidity of the '480 Patent)

56. MSN repeats and incorporates by reference each of the foregoing paragraphs of MSN's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

57. This counterclaim arises under the Patent Laws of the United States, Title 35 United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq*. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between MSN and Counterclaim Defendant concerning the validity of the claims of the '480 patent.

58. Counterclaim Defendant alleges ownership of the '480 patent and asserts that the commercial manufacture, use, sale and/or offer for sale of the MSN ANDA Product would infringe one or more claims of the '480 patent.

59. MSN asserts that the manufacture, use, offer for sale, or sale of the MSN ANDA Product does not and will not infringe, either directly or indirectly, any valid claim of the '480 patent and that the claims of the '480 patent are invalid under one or more provisions of 35 U.S.C.

§§ 101, 102, 103, or 112, or other judicially-created bases for invalidation.

60. The '480 patent is invalid under one or more provisions of 35 U.S.C. §§ 100 *et seq.*, including 101, 102, 103, or 112, or other judicially-created bases for invalidation.

61. MSN reserves the right to provide additional prior art and bases for invalidity in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

62. MSN is entitled to a declaration that the claims of the '480 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, or 112, or other judicially created bases for invalidation.

PRAYER FOR RELIEF

WHEREFORE, MSN respectfully requests that the Court enter a Judgment and Order in its favor and against Counterclaim Defendant as follows:

(a) declaring that MSN has not infringed any valid and enforceable claim of U.S. Patent No. 7,732,615;

(b) declaring that the manufacture, use, offer to sell, importation, or sale of MSN's ANDA product would not infringe any valid or enforceable claim of U.S. Patent No. 7,732,615;

(c) declaring that the claims of U.S. Patent No. 7,732,615 are invalid;

(d) declaring that MSN has not infringed any valid and enforceable claim of U.S. Patent No. 10,646,480;

(e) declaring that the manufacture, use, offer to sell, importation, or sale of MSN's ANDA product would not infringe any valid or enforceable claim of U.S. Patent No. 10,646,480

(f) declaring that the claims of U.S. Patent No. 10,646,480 are invalid;

(g) declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding MSN its attorneys' fees, costs, and expenses in this action; and

(h) awarding MSN any further and additional relief as the Court deems just and proper.

SEITZ, VAN OGTROP & GREEN, P.A.

/s/ James S. Green, Jr.

James S. Green, Jr. (DE 4406)
222 Delaware Avenue, Suite 1500
Wilmington, DE 19801
302-888-7607
Attorney for Defendants

Dated: September 30, 2020